Ascension® PIP Instructions For Use

Caution: Sterile 

Caution: U.S. federal law restricts this device to sale by or on the order of a physician.

Ascension® PIP

Proximal Interphalangeal Joint Implant

HUMANITARIAN DEVICE: The Ascension PIP is authorized by Federal law for use in arthroplasty of the proximal interphalangeal (PIP) joint when the patient:

- Has soft tissue and bone that can provide adequate stabilization and fixation under high-demand loading conditions after reconstruction; and
- Needs a revision of a failed PIP prosthesis, or has pain, limited motion, or joint subluxation/dislocation secondary to damage or destruction of the articular cartilage.

The effectiveness of this device for this use has not been demonstrated.

1. DEVICE DESCRIPTION

The Ascension PIP is a two-component, bi-condylar, semi-constrained, total joint prosthesis designed to replace the proximal interphalangeal (PIP) joint of the hand. Each component has an articulating surface, a sub-articular collar, and an intramedullary stem. Two convex articulating surfaces on the proximal component engage with and glide on two mating concave articulating surfaces on the distal component. Both components are constructed of a pyrocarbon layer encasing a graphite substrate. The graphite substrate material contains a small amount (1 atomic percent) of tungsten that renders the material radiopaque so that Ascension PIP components are clearly visible on radiographs. Ascension PIP components are available in four sizes to accommodate various operative requirements. To ensure proper fitting to the patient, the proximal and distal component sizes are interchangeable; each component can be matched with an opposite component of the same size, one size smaller, or one size larger. Instrumentation, including x-ray templates and color-coded sizing trials, are available for proper size determination. Intramedullary broaches for each size implant are available to properly prepare the proximal and distal medullary canals. This will help to achieve a "press fit" between the stem of the device and the medullary canal of the bone. No bone cement is required.

2. INDICATIONS FOR USE

The Ascension PIP is indicated for use in arthroplasty of the proximal interphalangeal (PIP) joint when the patient:

- Has soft tissue and bone that can provide adequate stabilization and fixation under high-demand loading conditions after reconstruction; and
- Needs a revision of a failed PIP prosthesis, or has pain, limited motion, or joint subluxation/dislocation secondary to damage or destruction of the articular cartilage.

3. CONTRAINDICATIONS

- Inadequate bone stock at the implantation site
- Active infection in the PIP joint
- Nonfunctioning and irreparable PIP musculotendinous system
- Physical interference with or by other prostheses during implantation or use
- Procedures requiring modification of the prosthesis
- Skin, bone, circulatory and/or neurological deficiency at the implantation site

4. WARNINGS AND PRECAUTIONS

WARNINGS:

- Do not modify the Ascension PIP implant in any manner. Reshaping the implant using cutters, grinders, burrs, or other means will damage the structural integrity of the device and could result in implant fracture and/or particulate debris.
- Do not match proximal and distal component sizes except as indicated in the following table. The wear behavior of component size combinations designated "Do Not Match" has not been evaluated, and is unknown.

Allowable Ascension PIP Component Size Combinations

		Proximal Component			
		Size 10	**Size 20**	**Size 30**	**Size 40**
Distal Component	**Size 10**	✓	✓	Do Not Match	Do Not Match
	Size 20	✓	✓	✓	Do Not Match
	Size 30	Do Not Match	✓	✓	✓
	Size 40	Do Not Match	Do Not Match	✓	✓

- Do not grasp the Ascension PIP implant with metal instruments, or instruments with teeth, serrations, or sharp edges. Implants should be handled only with

instrumentation provided by Ascension Orthopedics. Ascension PIP implants are made of pyrocarbon, which is a ceramic-like material. Mishandling implants could cause surface damage and reduce their strength, and could result in implant fracture and/or particulate debris.

- Do not use Ascension PIP components in combination with proximal and distal components from other products. The wear behavior of Ascension PIP components against proximal and distal component from other products has not been evaluated, and could damage the structural integrity of the device and result in implant fracture and/or particulate debris.

PRECAUTIONS

- Do not use the Ascension PIP in a joint where soft tissue reconstruction cannot provide adequate stabilization. Similar to the natural joint, the Ascension PIP attains stabilization from the surrounding capsuloligamentous structures. If soft tissue reconstruction cannot provide adequate stabilization, the device may subluxate or dislocate, lateral or longitudinal deformities may occur, or minimal motion or loss of motion may occur.
- Obtain proper training prior to use. Surgeons should obtain training from a qualified instructor prior to implanting the Ascension PIP to ensure thorough understanding of the indications, implantation and removal techniques, instrumentation, and post-operative rehabilitation protocol.
- Inspect the articulating surfaces of the Ascension PIP to insure they are clean and free of all debris prior to use. Foreign debris could result in excessive wear.
- Do not resterilize this device. Resterilization could lead to mishandling and surface damage that could result in implant fracture and/or particulate debris.
- Do not reuse this device. Any implant that has been damaged, mishandled, or removed from the sterile field may have surface damage that could result in implant fracture and/or particulate debris and should be discarded.
- Do not use excessive impact force on the broach. Excessive impact force may cause bone fracture. Remove and reinsert broach frequently to obtain maximum cutting efficiency.
- Do not use excessive impact force to seat the proximal sizing trial. Excessive impact force could cause sizing trial fracture. The sizing trial collar should abut the osteotomy after 2 impacts. If not, re-broach to increase cavity size and/or remove additional bone to provide clearance for the saddle area.
- Do not use excessive impact force to remove the proximal sizing trial. Excessive impact force could cause sizing trial fracture. If possible, the sizing trial should be removed without the use of a hammer. If a sizing trial does fracture, and it is not possible to easily remove the remaining stem fragment, a k-wire driven into the fragment may provide sufficient purchase for removal. Then, re-broach to increase cavity size and/or remove additional bone to provide clearance for the saddle area.

- Do not use excessive impact force to seat the implant components, especially if there has been a prior sizing trial fracture. Excessive impact force could cause component fracture. The component collar should abut the osteotomy after 2 impacts. If not, re-broach to increase cavity size or remove additional bone to provide clearance for the saddle area on the proximal component.

5. STERILITY

This implant has been sterilized by moist heat. If either the implant or the package appears damaged, or if sterility is questioned for any reason, the implant should not be used. Resterilization of this product is not recommended.

6. ADVERSE EFFECTS

The Ascension PIP has been used clinically in Europe, Canada, Australia and South Africa. Through December 31, 2001, 164 devices have been implanted. No serious adverse events or complications have been reported for these devices. There have been reports of intra-operative complications as summarized in the following table. All of these complications were uneventful and were resolved immediately. The fractured proximal sizing trials and components were removed and new components were successfully inserted, while the bone fractures were grossly stable and the medullary canals ultimately were properly prepared and implant components were successfully inserted. No sequelae have been reported for any of these complications.

Summary of Ascension PIP Adverse Events and Complications

	Implants (%) n = 164
Bone fracture (intra-operative)	3 (1.8%)
Proximal sizing trial fracture (intra-operative)	6 (3.7%)
Proximal component fracture (intra-operative)	3 (1.8%)

Information on these minor intra-operative complications was acquired and evaluated in accordance with the sponsor's ISO 9001 compliant Customer Feedback System. The severity and affect on the patient's health due to the adverse event was determined by follow-up communication with the source of the information. For complications summarized in the table above, no reports of sequelae were received over the course of this follow-up communication. The mean time and range of this follow-up communication was 28 days post-operative (range 13 – 54 days).

In addition, although not intended for use in the PIP joint, clinical results and adverse effects for the Pyrocarbon metacarpophalangeal (MCP) implant have been reported in the premarket approval application (PMA) for the Ascension MCP.[1] Please note that the "Pyrocarbon MCP" is an earlier version of the Ascension MCP that was used clinically to support the safety and

[1] PMA P000057, approved on November 19, 2001.

effectiveness of the Ascension MCP. Adverse effects for the Ascension PIP may be similar to those reported for the Pyrocarbon MCP because both devices share numerous identical attributes including design concept, construction, materials, and insertion and fixation methods. In addition, the primary objectives of PIP total joint arthroplasty are identical to those of MCP total joint arthroplasty, namely, relief of pain due to articular damage or destruction, and improvement in joint range of motion. Similarities between the Ascension PIP and Pyrocarbon MCP are further elaborated below in section 7 (Clinical Experience). Reported adverse effects identified below are those observed while using the Pyrocarbon MCP device.

PYROCARBON MCP REPORTED ADVERSE EFFECTS

In a retrospective case history review, 53 patients received 147 Pyrocarbon MCP prostheses and had last evaluations at an average of 8.5 years (range 1.7 months – 17.2 years) after implantation. The most commonly reported adverse events were:

- Recurrent deformity;
- Subluxation / dislocation;
- Re-operation for soft tissue reconstruction;
- Implant removal
- Implanted joint pain; and
- Synovitis.

A detailed discussion and complete list of the frequency and rate of complications and adverse events identified for the Pyrocarbon MCP implant is provided below in section 7 (Clinical Experience).

POTENTIAL ADVERSE EFFECTS

Potential adverse effects associated with total joint prostheses and surgery in general include, but are not limited to:

- Pain;
- Bleeding;
- Infection;
- Swelling;
- Damage to surrounding blood vessels, nerves, or soft tissue;
- Implant migration within the bones;
- Implant loosening;
- Excessive implant wear and particulate debris;
- Allergic or foreign body reaction;
- Implant fracture;
- Bone fracture;
- Implant subluxation or dislocation;
- Finger deformity (radial or ulnar deviation, supination or pronation);
- Reduction or loss of joint motion;
- Loss of finger or hand function; or
- Lengthening or shortening of the finger.

These adverse effects may lead to additional surgery and could result in:

- Implant removal;
- Joint fusion;
- Amputation; or
- Death

7. CLINICAL EXPERIENCE

The clinical use of the Ascension PIP has been summarized in Section 6 (Adverse Effects). In addition, although not intended for use in the PIP, clinical results and adverse effects for the Pyrocarbon metacarpophalangeal (MCP) implant have been reported in the PMA for the Ascension MCP.[2] Please note that the "Pyrocarbon MCP" is an earlier version of the Ascension MCP that was used clinically to support the safety and effectiveness of the Ascension MCP. As shown in the following table, the Ascension PIP has a number of features that are identical to the Pyrocarbon MCP. Identical characteristics include anatomic design concept, construction, materials, and insertion and fixation methods. In addition, the primary objectives of PIP total joint arthroplasty are identical to those of MCP total joint arthroplasty, namely, relief of pain due to articular damage or destruction, and improvement in joint range of motion.

Comparison of Ascension PIP and Pyrocarbon MCP Design Attributes

Attribute	Ascension PIP	Pyrocarbon MCP
two-component, total joint implant	yes	yes
semi-constrained articulation	yes	yes
articulation type	ball-and-cup	bi-condylar
proximal component bi-planar collar	yes	yes
distal component uni-planar collar	yes	yes
intramedullary stem	yes	yes
press-fit insertion	yes	yes
direct bone apposition fixation	yes	yes
pyrocarbon construction	yes	yes
graphite substrate	yes	yes

Therefore, because of these similarities, the clinical safety outcomes for the Pyrocarbon MCP are summarized below.

PYROCARBON MCP REPORTED ADVERSE EFFECTS

Complications and Adverse Events

In a retrospective case history review, 53 patients received 147 Pyrocarbon MCP prostheses and had last evaluations at an average of 8.5 years (range 1.7 months – 17.2 years) after implantation. The patient population consisted of 45 females and 8 males with a mean age of 57.5 years (range

[2] PMA P000057, approved on November 19, 2001.

21 – 78 years). Patients were diagnosed with one of four conditions: 43 (81%) patients had rheumatoid arthritis (RA), 2 (4%) had systemic lupus erythematosus (SLE), 5 (9%) had arthritis due to trauma (TA), and 3 (6%) had osteoarthritis (OA). For patients diagnosed with RA or SLE, the mean time from diagnosis until implantation of the first Pyrocarbon MCP was more than 16 years (range 3-36 years).

The most commonly reported adverse events were:

- Recurrent deformity;
- Subluxation / dislocation;
- Re-operation for soft tissue reconstruction;
- Implant removal;
- Implanted joint pain; and
- Synovitis

A complete list of the frequency and rate of complications and adverse events identified for the Pyrocarbon MCP implant is shown in the table below.

Pyrocarbon MCP Complications and Adverse Events

Complication / Adverse Event	Implants (N = 147)	% Implants	Patients (N = 53)	% Patients
Recurrent Deformity	49	33%	20	38%
Subluxation/Dislocation	31	21%	17	32%
Soft-tissue Re-operation	22	15%	11	21%
Implant Removal	21	14%	11	21%
Implanted joint pain	13	9%	11	21%
Synovitis	24	16%	10	19%
Stiffness / Loss of Motion	12	8%	6	11%
Subsidence	9	6%	6	11%
Loosening	7	5%	5	9%
Black Tissue Stain	7	5%	4	8%
Implant modification	5	3%	3	6%
Radiographic changes:				
lucency	4	3%	3	6%
sclerosis	1	1%	1	2%
heterotopic bone	2	1%	2	4%
cyst	1	1%	1	2%
erosion	2	1%	1	2%
Superficial Wound Infection	--	--	2	4%
Sensory Abnormality	3	2%	2	4%
Excessive erythema	2	1%	2	4%
Implant Fracture:				
in vivo fracture	0	0%	0	0%
intra-op fracture:				
at implantation	4	3%	4	8%
at removal	6	4%	3	6%
Bone Fracture:				
in vivo fracture	0	0%	0	0%
intra-op fracture	3	2%	2	4%

Implant Removals

A total of 21 (14%) Pyrocarbon MCP implants were removed from 11 (21%) patients. No implants were removed for implant fracture or clinical complications such as bone fracture, infection, sensory abnormality, allergic or foreign body reaction, iatrogenic complications or wound complications. Three (2%) implants were removed for loosening while 18 implants (12%) were removed for deformity associated with disease progression related to RA/SLE (extensor lag, flexion contracture, ulnar deviation, subluxation or dislocation). All removed implants were successfully revised; fifteen were replaced with silicone spacers, four Pyrocarbon MCP implants were reinserted with bone cement, and two new Pyrocarbon MCP implants were used. Of the 21 implants that were removed, 6 implants were removed less than 1 year after implantation; 9 implants were removed between 1 and 5 years after implantation; and 6 implants were removed greater than 5 years after implantation (range 5-11 years).

Summary of Implant Removals

	All Diagnoses (N=53 patients)	OA/Trauma (N=8 patients)	RA/SLE (N=45 patients)
Number of Implants	147	9	138
Number of Removals	21 (14%)	1 (11%)	20 (14%)
Reason for Removal			
Fracture	0 (0%)	0 (0%)	0 (0%)
Loosening, Subsidence, Migration	3 (2%)	1 (11%)	2 (1%)
Clinical Complication	0 (0%)	0 (0%)	0 (0%)
Disease Progression	18 (12%)	0 (0%)	18 (13%)

Soft Tissue Re-Operations

Eleven (11) soft tissue re-operation procedures were performed on a 22 (15%) joints in 11 (21%) Pyrocarbon MCP patients. Procedures were performed to correct recurrent MCP joint deformities such as implant subluxation/dislocation, ulnar/radial deviation, extension lag or loss of motion, or extension contracture. All but one of the soft tissue re-operations was on RA/SLE patients. Three (3) of the 22 implants were eventually removed, all due to recurrent subluxation or dislocation. Sixteen (16) of the 22 joints were operated on less than 1 year post-implantation.

Summary of Soft Tissue Re-operations

	All Diagnoses (N=53 patients)	OA/Trauma (N=8 patients)	RA/SLE (N=45 patients)
Number of Implants	147	9	138
Number of Implants Re-operated	22 (15%)	1 (11%)	21 (15%)
Reason for Re-operation			
Subluxation / Dislocation	7 (5%)	0 (0%)	7 (5%)
Ulnar / Radial Deviation	7 (5%)	1 (11%)	6 (4%)
Extension Lag / Loss of Motion	5 (3%)	0 (0%)	5 (4%)
Extension Contracture	3 (2%)	0 (0%)	3 (2%)

Intraoperative Implant Fractures

There were a total of 10 intraoperative Pyrocarbon MCP implant fractures, i.e., fractures that occurred during either implantation or revision of the device. Four of the 10 intraoperative fractures occurred during the implantation of 295 components for a rate of 1.4% (4/295). In 3 of the 4 cases, the fractured component was easily removed and a new Pyrocarbon MCP component was inserted while in the fourth case, the fragment was left *in situ* and a silicone spacer was inserted. Six of the 10 fractures occurred during implant revision and removal of 42 components (21 devices) for a rate of 14% (6/42). Five of these fractured devices were replaced with a silicone spacer while the 6th fractured device was essentially intact and was reinserted with bone cement. All intraoperative fractures were uneventful and no *sequelae* resulted.

Black Staining of Tissue and Synovitis
There were reports of black staining of tissue and synovitis. However, in the tissue samples evaluated by the histopathologist, there were no reports of an adverse tissue reaction to the Pyrocarbon MCP joint implant, carbon particles, or "fine particulate matter."

Black Staining of Tissue
A total of 7 implants caused black stained tissue in 4 of 53 patients for a rate of 7.5% (4/53). Four (4) events occurred during removal of implants from each finger on one patient's hand. All four fractured implants were removed by drilling them out of the bone. After the drilling process, black stained tissue was observed in each finger. No tissue samples were taken from this patient.

In addition, there were 3 events observed during operations to remove implants that were potentially loose in 3 patients. Tissue samples from these three patients were excised during removal for histopathologic examination. The histopathologist concluded that the tissue did not reveal any negative tissue reaction. All implants were revised. Two (2) implants were revised to silicone spacers and 1 Pyrocarbon MCP implant was reinserted with cement.

Synovitis
A total of 24 synovitis events were reported for 10 patients for a rate of 19% (10/53). Tissue samples were available for examination from 5/24 joints including samples from 2 RA patients and one Trauma patient. The histopathologist's review concluded that there was no adverse tissue reaction to the implant, carbon particles, or "fine particle matter" in these samples.

8. SURGICAL PROCEDURE

A Surgical Technique manual is available which outlines the basic procedure for device implantation and removal and the use of specialized surgical instrumentation, which will provide optimum implantation and reconstruction results.

Meticulous preparation of the implant site and selection of the proper size implant increase the potential for successful reconstruction. A complete set of instruments for each type of implant is available to aid bone preparation and reduce the operative time. It is suggested that the proper size implant be removed from its sterile package only after the implant site has been prepared and properly sized.

Anatomical dimensions limit the physical size of the device that can be implanted. In most cases, the largest possible implant should be selected which, in the opinion of the surgeon, does not require excessive bone resection or in any way limits function or healing.

9. POST-OPERATIVE THERAPY

A Post-Operative Therapy Protocol is available which summarizes post-operative care guidelines. For further information, please contact Ascension Orthopedics' Customer Service toll-free at 877-370-5001.

10. TRAINING

Surgeons should obtain training from a qualified instructor prior to implanting the Ascension PIP to ensure thorough understanding of the indications, implantation and removal techniques, instrumentation, and post-operative rehabilitation protocol. Please contact Ascension Orthopedics' Customer Service toll-free at 877-370-5001 to arrange training with a qualified instructor.

Disclaimer of Warranties

Ascension Orthopedics has no control over the conditions under which the device is used, the diagnosis of the patient, or the methods or procedures used for implantation. Therefore, Ascension Orthopedics makes no warranty or guaranty, expressed or implied, of the implant or accessory instruments other than the warranty that at time of manufacture, reasonable care was used in their manufacture of this device.

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